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PTO/SB/21 (09-04)

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## TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

<b>TRANSMITTAL FORM</b> <i>(to be used for all correspondence after initial filing)</i>	Application Number <b>10/806,515</b>	
	Filing Date <b>March 22, 2004</b>	
	First Named Inventor <b>Tom F. LUE</b>	
	Art Unit <b>1646</b>	
	Examiner Name <b>Not Yet Assigned</b>	
Total Number of Pages in This Submission	<b>6</b>	Attorney Docket Number <b>220022001610</b>

### ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement (3 pages) <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): PTO/SB/08a/b Form (1 page plus duplicate) References (15) Return Receipt Postcard
Remarks		

CUSTOMER NO. 25225

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	MORRISON & FOERSTER LLP		
Signature			
Printed name	Brenda J. Wallach		
Date	April <u>21</u> , 2006	Reg. No.	45,193

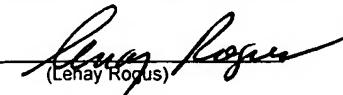
I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV 743885382 US, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: April 24, 2006

Signature: (Lenay Rogus)

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV 743885382 US, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

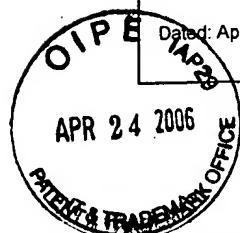
Dated: April 24, 2006

Signature: 

(Lehay Rogers)

Patent

Docket No. 220022001610



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Tom F. LUE et al.

Serial No.: 10/806,515

Filing Date: March 22, 2004

For: METHODS AND COMPOSITIONS FOR  
PREVENTING AND TREATING MALE  
ERECTILE DYSFUNCTION AND  
FEMALE SEXUAL AROUSAL  
DISORDER

Examiner: Not Yet Assigned

Group Art Unit: 1646

### SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO/SB/08a/b. Copies of non-patent literature documents are submitted herewith. The Examiner is requested to make these documents of record.

This Information Disclosure Statement is submitted:

- With the application; accordingly, no fee or separate requirements are required.
- Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
  - A fee is required. A check in the amount of \_\_ is enclosed.
  - A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
  - A Certification under 37 C.F.R. § 1.97(e) is provided above; accordingly; no fee is believed to be due.
- After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
  - A Certification under 37 C.F.R. § 1.97(e) is provided above and a check in the amount of \_\_ is enclosed.
  - A Certification under 37 C.F.R. § 1.97(e) is provided above and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.)

Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist;

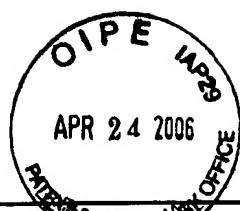
(iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal form is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief (such as payment of a fee under 37 C.F.R. § 1.17 (p)) is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petition and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing 220022001610.

Dated: April 21, 2006

Respectfully submitted,

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Substitute for Form 1449/PTO				Complete if Known	
				Application Number	10/806,515
				Filing Date	March 22, 2004
				First Named Inventor	Tom F. LUE
				Art Unit	1646
				Examiner Name	Not Yet Assigned
Sheet	1	of	1	Attorney Docket Number	220022001610

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
1.	US-5,770,228	06-23-1998	Edwards et al.		
2.	US-5,770,606	06-23-1998	El-Rashidy et al.		
3.	US-6,037,320	03-14-2000	Rosenthal		
4.	US-2002/0032153	03-14-2002	Whitehouse		

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)			
					<sup>1</sup> <sup>3</sup>

\*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			<sup>1</sup> <sup>2</sup>
5.	BASKIN et al., The Journal of Urology (1999) 162:1015-1020				
6.	BERMAN et al., The Journal of Urology (2003) 170:2333-2338				
7.	BURNETT et al., The Journal of Urology (1997) 158:75-78				
8.	CHATTOPADHYAY et al., Gene Therapy (2005) 12:1377-1384				
9.	DASGUPTA et al., The Journal of Urology (2004) 171:1189-1193				
10.	GHOLAMI et al., The Journal of Urology (2003) 169:1577-1581				
11.	Gray's Anatomy, 38 <sup>th</sup> ed., (1999) Chapter 3: Embryology and Development, Reproductive System, pp. 210, 214-216				
12.	MELMAN, International Journal of Impotence Research (2006) 18:19-25				
13.	MUSICKI et al., Biology of Reproduction (2004) 70:282-289				
14.	PESSINA et al., Endocrinology (2006) 147:61-69				
15.	REHMAN and MELMAN, The Journal of Urology (1999) 161:200-206				
16.	VIAGRA (sildenafil citrate) <a href="http://www.viagra.com/">http://www.viagra.com/</a> web page visited April 6, 2006				
17.	YILMAZ et al., The Journal of Urology (2002) 167:616-620				
18.	YOON et al., International Journal of Impotence Research (2005) 17:33-38				
19.	ZIPPE et al., International Journal of Impotence Research (2006) 18:1-18				

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	Date Considered
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